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SERIAL NO. 10/625,826

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Appellant:	Wagner et al.	Examiner:	Prone, C.
Serial No.:	10/625,826	Group Art Unit:	3738
Filing Date:	July 23, 2003	Docket No.:	GUID.619PA (03-521)
Title:	TUNNELING TOOL WITH SUBCUTANEOUS TRANSDERMAL ILLUMINATION		

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Appeal Brief - Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, on February 26, 2007.

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REPLY BRIEF

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Sir:

This Reply Brief is submitted pursuant to 37 C.F.R. §41.41 for the above-referenced patent application in response to the Examiner's Answer dated December 26, 2006.

This brief replicates the Appeal Brief filed on November 1, 2006, with the only exceptions being this cover page and the Argument section (Section VII), which addresses the comments provided in the "Response to Argument" section of the Examiner's Answer.

No fee is believed to be required for the filing of this Reply Brief; however, if it is determined that a fee is necessary, authority is given to charge/credit deposit account 50-3581 (GUID.619PA) in support of this filing.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Cardiac Pacemakers, Inc.



II. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any related appeals, interferences or judicial proceedings that would have a bearing on the Board's decision in the instant appeal.

III. STATUS OF CLAIMS

Claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63 are pending, each of which is presented for appeal. Each of the pending Claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63 has been finally rejected by the Examiner's action dated March 9, 2006, from which Appellant appeals.

The pending Claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63 under appeal may be found in the attached Claims Appendix.

IV. STATUS OF AMENDMENTS

No amendments have been presented subsequent to the final rejection dated March 9, 2006.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to a subcutaneous dissection tool for deploying subcutaneous cardiac devices, therapies, and combinations thereof, and that is capable of transdermal illumination during dissection. As the light emanates from the tool through a patient's tissue and skin, a clinician may use the tool to identify the location of the tool along the dissection path and/or the depth of the tool. The illumination is used as a visual aid to identify the location of the tool for improved navigation and placement of subcutaneous leads.

One embodiment of the present invention is directed to a dissection tool. *See, e.g.*, Claim 1; Figs. 2, 5A-B, and 6A-C; and the corresponding discussion in the Specification at page 11, line 12 through page 12, line 26, and page 14, line 12 through page 16, line 21. The dissection tool (*e.g.*, 290) includes a handle (*e.g.*, 260) having a proximal end and a distal end and an elongated dissecting member (*e.g.*, 280) having a proximal end and a distal end. The elongated dissecting member extends from the distal end of the handle, and a light source (*e.g.*, 282) is provided at the distal end of the dissecting member. The light source is adapted to provide a visible locating reference through the skin.

Other embodiments may be directed to a dissection tool having a handle and an elongated dissecting member as discussed above, as well as means for illuminating a path of subcutaneous tissue dissection. *See, e.g.*, Claim 44; Figs. 2, 4A-B, and 5B; and the corresponding discussion in the instant Specification at page 11, line 12 through page 12, line 26, page 13, line 23 through page 14, line 11, and page 14, line 16 through page 15, line 5. The means for illuminating a path of subcutaneous tissue dissection (*e.g.*, 282) may include, for example, a light source such as an incandescent bulb, a light emitting diode (LED), a fluorescent light source, a vapor lamp, an arc lamp, a plasma light source, and a halogen bulb. The means for illuminating a path may also include a switch (*e.g.*, 275) such as a pull-tab, a physical switch, or a computer controlled switch including a voice-activated relay. Various power sources (*e.g.*, 272) may also be included in the means for illuminating a path such as a storage battery, a fuel cell, a rechargeable battery, an electrochemical cell. Both a switch and power source may be located within the dissection tool or located external to the tool. The means for illuminating a path may also include light filters and a light pipe (*e.g.*, 550).

Another embodiment of the present invention is directed to a dissection tool. *See, e.g.*, Claim 53; Fig. 2; and the corresponding discussion in the Specification at page 11, line 12

through page 12, line 26. The dissection tool (*e.g.*, 290) includes a handle (*e.g.*, 260) having a proximal end and a distal end and an elongated dissecting member (*e.g.*, 280) having a proximal end and a distal end. The elongated dissecting member extends from the distal end of the handle and includes at least one curved portion (*e.g.*, 280). An optical location indicator (*e.g.*, 282) is provided at the distal end of the dissecting member and is adapted to provide a visible indication of the distal end of the dissecting member through the dermis.

As required by 37 C.F.R. § 41.37(c)(1)(v), a concise explanation of the subject matter defined in each of the independent claims involved in the appeal is provided herein. Appellant notes that representative subject matter is identified for each of these claims; however, the abundance of supporting subject matter in the application prohibits identifying all textual and diagrammatic references to each claimed recitation. Appellant thus submits that other application subject matter, which supports the claims but is not specifically identified above, may be found elsewhere in the application. Appellant further notes that this summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and their legal equivalents for a complete statement of the invention.

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63 stand rejected under 35 U.S.C. §102(b) based on Chen *et al.* (U.S. Pat. No. 5,445,608).

VII. ARGUMENT

The rejection under 35 U.S.C. §102(b) is improper because Chen *et al.* fails to correspond to each of the limitations of the claimed invention.

Appellant maintains the traversal of the §102(b) rejection because Chen has not been shown to correspond to each of the claimed limitations, notably an elongated dissecting member and a light source adapted to provide a visible locating reference through the skin, in the requisite detail. The Examiner's reliance on a newly-cited portion of Chen and a newly-purported definition of "dissecting" is improper and unsupported.

The Examiner allegedly found a definition for "dissecting" on the Internet as reading "dividing or separating parts of an animal" and has interpreted "separating parts of an animal" as corresponding to separation of tissue by the implantation of a light source. *See*, description of relied-upon Figs. 2A-2C at column 5, lines 57-65 of Chen. This newly-asserted dissecting member of Figs. 2A-2C is not the originally-asserted dissecting member 262 of Fig. 17 as identified at page 3 in the "Grounds of Rejection" of the Examiner's Answer. No correspondence has been asserted or shown as to how this newly-cited portion of Chen corresponds to any of the other limitations of at least Appellant's independent Claims 1, 44 and 53. Without a presentation of correspondence to each of the claimed limitations in as complete detail as is contained in the claims, the §102 rejection should not be maintained.

Moreover, if the Examiner is relying on this newly-cited portion of Chen, such reliance would appear to be a new ground of rejection. Appellant notes that any new grounds of rejection must be prominently identified in the "Grounds of Rejection" section of the Examiner's answer. MPEP §§1207.03 and 1207.02. No such new ground has been identified. Thus, any reliance on the newly-cited portions of Chen is improper.

The Examiner's reliance on an extrinsic dictionary definition is also improper. Appellant notes that while claims must be interpreted broadly, such interpretation must be reasonable in light of the Specification. *See, e.g., In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004); *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); and MPEP §2111.01(I). Appellant's Specification indicates that the dissecting member is used to perform small diameter blunt tissue dissection of subdermal layers and, for example, may be a long metal rod similar to

conventional trocars. *See, e.g.*, page 11, lines 5-8. A definition of “separating parts of an animal” would not be reasonable in light of Appellant’s disclosure of blunt tissue dissection. Again, no evidence has been presented that the flexible catheter 262 would correspond in any way to the claimed dissecting member, such as by performing blunt tissue dissection. The Examiner’s further assertion that Chen discloses that “the device” can be stiffened is erroneous. The cited portion at column 19 merely discloses that a clinician would like a flexible catheter/implantable probe to be able to be stiffened but nowhere does Chen teach that flexible catheter 262 can be stiffened as asserted. Thus, the Examiner’s reliance on an external definition is improper, and Chen has still not been shown to correspond to claimed invention.

The Examiner’s interpretation of the asserted definition is also not reasonable. The Examiner’s interpretation of “separating animal parts” as meaning “separating tissue” ignores the plain meaning of the terms used in the definition and is overly broad. In the context of dissection, the meaning of separating animal parts would not be construed to mean the mere displacement of tissue. Based upon the Examiner’s interpretation, any item that occupies space and displaces tissue would be “dissecting.” Such an interpretation is not reasonable generally, or in light of the instant Specification.

Moreover, the Examiner’s reliance on the newly-purported dictionary definition is unsupported. While the definition allegedly was found on the Internet in an “Online Medical Dictionary”, no website or URL has been identified that Appellant may use to verify or review such definition. The reliance on new evidence without providing Appellant the opportunity to review and respond is inappropriate.

Appellant maintains that because no evidence has been shown that Chen’s flexible catheter is a dissecting member, as claimed, because Chen’s teachings contradict any assertion that the flexible catheter would correspond to the claimed limitations, and because no further teachings of Chen have been properly shown to correspond to each of the claimed limitations in the requisite detail, the §102 rejection is improper.

In addition, contrary to the Examiner’s assertions at page 5 of the Examiner’s Response, Appellant did not argue in the Appeal Brief filed on November 1, 2006, or at any other time in the prosecution of this application, that Chen fails to disclose a handle or that Chen fails to disclose a light source. Rather, Appellant argued, and maintains, that because Chen fails to disclose a dissecting member, as discussed above, Chen fails to disclose an elongated

dissecting member extending from the distal end of a handle and a light source or an optical location indicator provided at the distal end of a dissecting member, as claimed, for example, in Claims 1 and 53. The Examiner has inappropriately mischaracterized Appellant's arguments.

Consistent with an accurate characterization of the previous argument, Appellant maintains that Chen does not teach a light source adapted to provide a visible locating reference through the skin. The Examiner's assertion at page 5 of the Examiner's Response that Chen teaches "that the device may be seen during implantation with the use of fluoroscopy and imaging" is unsupported and incorrect. The provided citation to column 19, lines 17-19 of Chen merely states that a clinician would like to have a device that could be monitored using fluoroscopy or other imaging modality. There is no indication that Chen's device is monitored using such methods. Also the assertion that Chen's device "may be seen during implantation" does not assert or provide the requisite detailed evidence to show that Chen actually teaches a light source adapted to provide a visible locating reference through the skin. For example, the "other imaging modality" could refer to imaging without using visible light such as ultraviolet light. Appellant maintains that since Chen teaches that a light source is activated after the light source is placed at a treatment site within the patient to provide local irradiation of tissue at the treatment site, the location of the light source (or probe) is already known. *See, e.g.*, column 11, lines 46-55. Thus, it has not been shown, in the requisite detail, that any of Chen's light sources would be adapted to provide a visible locating reference, as claimed.

Appellant respectfully submits that Chen does not teach each of the claimed limitations and therefore fails to support the §102(b) rejection of each of the rejected claims. Chen at least fails to teach an elongated dissecting member extending from the distal end of a handle and a light source provided at the distal end of a dissecting member, as claimed. Chen does not teach an apparatus that corresponds to the claimed invention in the requisite detail. *See, Richardson v. Suzuki Motor Co.* For at least these reasons, Appellant requests that the rejection be reversed.

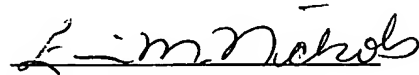
VIII. CONCLUSION

In view of the above, Appellant respectfully submits that the claimed invention is patentable over the cited reference and that the rejection of claims 1-5, 8-11, 44, 46, 47, 49, 50, 53-58 and 61-63 should be reversed. Appellant respectfully requests reversal of the rejection as applied to the appealed claims and allowance of the entire application.

Authorization to charge the undersigned's deposit account is provided on the cover page of this brief.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Erin M. Nichols", written over a horizontal line.

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IX. CLAIMS APPENDIX

1. A dissection tool, comprising:
 - a handle having a proximal end and a distal end;
 - an elongated dissecting member having a proximal end and a distal end, the elongated dissecting member extending from the distal end of the handle; and
 - a light source provided at the distal end of the dissecting member, the light source adapted to provide a visible locating reference through the skin.
2. The dissection tool of claim 1, further comprising a battery adapted to provide power to the light source.
3. The dissection tool of claim 1, further comprising a power line having a distal end extending from the light source and a proximal end extending to at least a surface of the handle, the proximal end of the power line coupled to a connector adapted to matingly engage a connector of an external power source.
4. The dissection tool of claim 1, further comprising a switch provided on the handle of the dissection tool, wherein the switch is adapted to toggle the light source off and on.
5. The dissection tool of claim 1, wherein the light source comprises a light emitting diode.
8. The dissecting tool of claim 1, further comprising a fluid channel system extending from the proximal end of the elongated dissecting member to the distal end of the elongated dissecting member, the fluid channel system terminating in a port system.
9. The dissecting tool of claim 8, wherein the fluid channel system is adapted to transport a pharmacological agent.

10. The dissecting tool of claim 9, wherein the pharmacological agent comprises one or more of an analgesic, an antibiotic, and an antiseptic agent.
11. The dissecting tool of claim 8, wherein a first fluid channel is adapted to transport irrigation fluid and a second fluid channel is adapted to transport a pharmacological agent.
44. A dissection tool, comprising:
a handle having a proximal end and a distal end;
an elongated dissecting member extending from the distal end of the handle; and
means for illuminating a path of subcutaneous tissue dissection.
46. The dissection tool of claim 44, further comprising means for providing internal power to the illuminating means.
47. The dissection tool of claim 44, further comprising means for switching the illuminating means between off and on states.
49. The dissection tool of claim 44, further comprising means for coupling light from an internal light source to the illuminating means.
50. The dissection tool of claim 44, wherein the illuminating means comprises a light emitting diode.
53. A dissection tool, comprising:
a handle having a proximal end and a distal end;
an elongated dissecting member extending from the distal end of the handle, the dissecting member having a proximal end, a distal end, and at least one curved portion; and
an optical location indicator provided at the distal end of the dissecting member and adapted to provide a visual indication of a location of the distal end of the dissecting member through the dermus.

54. The dissection tool of claim 53, wherein the elongated dissecting member has a curvature appropriate for dissection along a plane that follows a curvature of a rib-cage.

55. The dissection tool of claim 53, wherein the elongated dissecting member has a generally arcuate shape.

56. The dissection tool of claim 53, further comprising means for providing power to the optical location indicator.

57. The dissection tool of claim 53, further comprising means for switching the optical location indicator between off and on states.

58. The dissection tool of claim 53, wherein the optical location indicator comprises a light emitting diode.

61. The dissection tool of claim 53, further comprising a fluid channel system extending between the proximal and distal ends of the dissecting member, the fluid channel system terminating in a port system.

62. The dissection tool of claim 61, wherein the fluid channel system is adapted to transport a pharmacological agent.

63. The dissection tool of claim 62, wherein the pharmacological agent comprises one or more of an analgesic, an antibiotic, and an antiseptic agent.

X. EVIDENCE APPENDIX

None.

XI. RELATED PROCEEDINGS APPENDIX

None.